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10/771,730	02/04/2004	Akio Uchiyama	17415	4045

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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/771,730	UCHIYAMA ET AL.	
	Examiner	Art Unit	
	Jonathan G. Cwern	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,6,8,9,12-21,24,43,44 and 52-62* is/are pending in the application.

4a) Of the above claim(s) *52-62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,6,8,9,12-21,24,43,44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claims 2, 8, 12, 15-21, 24, and 43-44 are objected to because of the following informalities:

In claim 2, "the thrust generating state" should be changed as the term "state" has been removed from claim 1.

In claim 8, the phrase "has a diagnosis/cure device is selected" is grammatically confusing.

In claim 12, the phrase "and any combination of devices thereof" is unclear. This statement appears at the end of the lines regarding the thrust generating amount, which discusses frequencies and not necessarily devices. It appears this may have been referring to the thrust generating mechanism which could be any of a group of devices. This should be clarified.

Claims 15-21, 24, and 43-44 improperly depend from cancelled claims. For purposes of examination, they have been considered dependent on claim 1.

Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 5-6, 8-9, 12-21, 24, and 43-44 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 8-18, and 65-68 of copending Application No. 10/910738. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be an obvious modification to generate thrust so as to cause the endoscope body to rock about an axis.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3, 5-6, 8-9, 12-21, 24, and 43-44 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5-7, 9-23, and 26-27 of copending Application No. 11/823598. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be an obvious modification to design the device to meet specific

criteria such as a diameter-reduced portion or the spiral structure disposed inside the main body.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3, 5-6, 8-9, 12-21, 24, and 43-44 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10-24 and 26-27 of copending Application No. 11/230201. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be an obvious modification to select a specific speed for the thrust generation or to generate thrust to cause the endoscope to repetitively advance and retreat.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5-6, 9, 12, 14-18, 20-21, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishiyama et al. (Spiral-type Micro-machine for Medical Applications, 2000 International Symposium on Micromechatronics and Human Science, IEEE, 2000) in view of Strommer et al. (US 6233476) and Takizawa et al. (US 2003/0020810).

Ishiyama et al. disclose a spiral-type magnetic micro-machine. The device comprises a magnet and a spiral blade which can be controlled by a rotational magnetic field. The rotation generates forward or backward thrust by the spiral blade based on the rotational plane of the field. The swimming direction of the machine can therefore be controlled by changing the direction of the rotational magnetic field. Also, the velocity of the device can be controlled by changing the frequency of the field (page 65-68). While no explicit mention is made of an input unit or control unit, these are inherent, as something must be inputting the data to change the direction and frequency of the magnetic field. Input units are well known in the art and are capable of inputting any sort of data which could aid in the control of the device, such as the strength or direction of the magnetic field, in order to move the device a desired distance at a

desired speed. Ishiyama et al. fail to show a storing unit or direction detecting unit and that the device is a medical apparatus inserted in the body cavity.

Strommer et al. disclose a medical positioning system. Strommer et al. teach the use of a storage unit and direction detecting unit. A location and orientation detector can detect the device, and store this data in the storage unit (column 13, line 49-column 14, line 38 and column 16, lines 14-23).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have detected the direction of the device as taught by Strommer et al., in the system of Ishiyama et al. Ishiyama et al. discuss navigating the device through a maze, by changing the direction of the device. While no mention is made of how the direction of the device is detected, it would be an obvious modification to include a direction detecting unit so as to control and maneuver the device as desired, with an understanding of its location. Furthermore, it would be obvious to include a storage device. Storage devices can be used to store a variety of data, such as image data or positional data.

Takizawa et al. disclose a capsule-type medical apparatus. Takizawa et al. teach the use of capsule type devices for medical systems. Takizawa et al. use a similar spiral design with magnetic field to move the device. The device further includes imaging means as is common in capsule-endoscope devices ([0159]-[0181]).

It would have been obvious to have modified or used the device of Ishiyama et al. as a medical apparatus in a patient as taught by Takizawa et al. Indeed, Ishiyama et al. note that their device shows great potential for running in human organs (page 68).

It would be an obvious design choice to one of ordinary skill in the art to position the magnet in the capsule, either at the end or at the center of gravity. Takizawa et al. teach that the magnet is positioned at the end of the capsule, however it would be an obvious design choice to one of ordinary skill in the art to position the magnet anywhere in the capsule so long as it does not negatively impact the use of the device.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ishiyama et al. (Spiral-type Micro-machine for Medical Applications, 2000 International Symposium on Micromechatronics and Human Science, IEEE, 2000) in view of Strommer et al. (US 6233476) and Takizawa et al. (US 2003/0020810) as applied to claim 1 above, and further in view of Yokoi et al. (US 2003/0023150).

Yokoi et al. disclose a capsule-type medical device and medical system. Yokoi et al. teach that a capsule-type device can be configured to deliver medicine, or to suck up body fluid ([0184]-[0186]).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have modified the combined device of Ishiyama et al., Strommer et al., and Takizawa et al. to deliver medicine or extract body fluid as taught by Yokoi et al. This is a common use of such capsule-type endoscopes, as they are in direct proximity to the organ which requires medicine, and thus are in a convenient position to deliver the medicine which is required for treatment.

Claims 13 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishiyama et al. (Spiral-type Micro-machine for Medical Applications, 2000 International Symposium on Micromechatronics and Human Science, IEEE, 2000) in view of Strommer et al. (US 6233476) and Takizawa et al. (US 2003/0020810) as applied to claims 1 and 3 above, and further in view of Frassica (US 5989230).

Frassica discloses a rotate to advance catheterization system. Frassica teaches that the image can be corrected for rotation for easier viewing (column 1, lines 30-35).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have modified the combined device of Ishiyama et al., Strommer et al., and Takizawa et al. to have corrected the image for rotation in order to provide a benefit to the person administering the procedure, by allowing the image to be more easily viewed.

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ishiyama et al. (Spiral-type Micro-machine for Medical Applications, 2000 International Symposium on Micromechatronics and Human Science, IEEE, 2000) in view of Strommer et al. (US 6233476) and Takizawa et al. (US 2003/0020810) as applied to claim 1 above, and further in view of Iddan (US 2002/0111544).

Iddan discloses a system and method for determining in vivo body lumen conditions. Iddan teaches the use of a motor to drive a motion producing device ([0043]).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have modified the combined device of Ishiyama et al., Strommer et al., and Takizawa et al. to use a motor to drive the device as taught by Iddan. There are a variety of methods well known in the art for moving a capsule within a patient, and any of those, including motion from a propeller driven by a motor, would be a suitable equivalent to the motion driving mechanisms of Ishiyama et al.

Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ishiyama et al. (Spiral-type Micro-machine for Medical Applications, 2000 International Symposium on Micromechatronics and Human Science, IEEE, 2000) in view of Strommer et al. (US 6233476) and Takizawa et al. (US 2003/0020810) as applied to claim 1 above, and further in view of Ouchi (US 6527705).

Ouchi discloses a fully swallowable endoscopic system. Ouchi teaches the use of an external power supply, and a device in the capsule which receives the signal from the power supply and delivers the power to the components within the capsule (column 7, lines 7-37).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have modified the combined device of Ishiyama et al., Strommer et al., and Takizawa et al. to use an external power supply as taught by Ouchi, in order to reduce the size of the device by eliminating a bulky power supply. This also can be safer for the patient in the case of the capsule becoming stuck inside. Techniques for providing power from devices external to the patient are well known in the art, and it

would be obvious to modify a capsule type device to use any sort of power supply system which appropriately powers the device.

Response to Arguments

Applicant's arguments filed 2/12/09 have been fully considered but they are not persuasive.

In regards to applicant's arguments that the prior art does not show the features in the independent claim, examiner respectfully disagrees. The modified device of Ishiyama et al. is capable of being moved through a maze, and within the human body one would be able to control the magnetic field to move the device in any direction.

In regards to applicant's arguments regarding means plus function language, it is still unclear whether or not applicant intends to invoke 112 sixth paragraph in those claims previously objected to.

In regards to applicant's arguments regarding the double patenting rejections, examiner respectfully disagrees. Although the conflicting claims are not identical, they are not patentably distinct from each other because it of obvious modifications.

Applicant's other amendments have overcome objections to the specification and drawings, as well as the 101 and 112 rejections.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan G. Cwern whose telephone number is (571)270-1560. The examiner can normally be reached on Monday through Friday 9:30AM - 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan G Cwern/
Examiner, Art Unit 3737

/BRIAN CASLER/
Supervisory Patent Examiner, Art Unit 3737